

# **Remedial Investigation/Feasibility Study Work Plan**

**Pines Area of Investigation  
AOC II  
Docket No. V-W-'04-C-784**

**Volume 5**

**Human Health Risk  
Assessment Work Plan**

**ENSR Corporation**

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## ACRONYMS

AAF	Absorption Adjustment Factors
ACS	American Cancer Society
AOC I	Administrative Order on Consent, 2003 and as amended, 2004; Docket No. V-W-03-730
AOC II	Administrative Order on Consent, 2004; Docket No. V-W-'04-C-784
ARAR	Applicable or Relevant and Appropriate Requirements
BCF	Bioconcentration Factor
bgs	below ground surface
BSAF	Biota-Sediment Accumulation Factor
CADD	Chronic Average Daily Dose
CAS	Chemical Abstracts Service
CCB	Coal Combustion By-Product
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CTE	Central Tendency Exposure
COC	Constituent of Concern
COPC	Constituent of Potential Concern
CSF	Cancer Slope Factor
CSM	Conceptual Site Model
DQL	Data Quality Level
EFH	Exposure Factors Handbook
ELCR	Excess Lifetime Cancer Risk
EPC	Exposure Point Concentration
ERA	Ecological Risk Assessment
FS	Feasibility Study
FSP	Field Sampling Plan
HASP	Health and Safety Plan
HEAST	Health Effects Assessment Summary Tables
HHRA	Human Health Risk Assessment
HI	Hazard Index
HQ	Hazard Quotient
IDEM	Indiana Department of Environmental Management
IDNL	Indiana Dunes National Lakeshore
IDNR	Indiana Department of Natural Resources
IEUBK	Integrated Exposure Uptake Biokinetic
IRIS	Integrated Risk Information System
LADD	Lifetime Average Daily Dose
MCL	Maximum Contaminant Level
MWSE	Municipal Water Service Extension
NCDC	National Climatic Data Center
NCEA	National Center for Environmental Assessment
NCP	National Contingency Plan

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NIPSCO	Northern Indiana Public Service Company
NRC	Nuclear Regulatory Commission
NWS	National Weather Service
OSWER	Office of Solid Waste and Emergency Response
PAH	Polycyclic Aromatic Hydrocarbon
PC	Permeability Constant
PCDD	Polychlorinated Dibenzodioxin
PCDF	Polychlorinated Dibenzofuran
PEF	Particulate Emission Factor
PM <sub>10</sub>	Particulate Matter of 10 Microns or Less in Diameter
PQL	Practical Quantitation Limit
PRG	Preliminary Remediation Goal
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
RAGS	Risk Assessment Guidance for Superfund
RAL	Removal Action Level
RBC	Risk-Based Concentration
RCRA	Resource Conservation and Recovery Act
RfC	Reference Concentration
RfD	Reference Dose
RI	Remedial Investigation
RI/FS	Remedial Investigation/Feasibility Study
RISC	Risk Integrated System of Closure
RME	Reasonable Maximum Exposure
S	Statistical Difference
SAP	Sampling and Analysis Plan
SMS	Site Management Strategy
SOW	Statement of Work
SQL	Sample Quantitation Limit
TBC	To Be Considered
TCDD	Tetrachlorodibenzo-p-dioxin
TEF	Toxic Equivalency Factor
TEQ	Toxic Equivalence Concentration
UCL	Upper Confidence Limit
URF	Unit Risk Factor
USEPA	U.S. Environmental Protection Agency
USGS	U.S. Geological Society
WHO	World Health Organization

### **DISCLAIMER**

This document is a document prepared under a federal administrative order on consent and revised based on comments received from the U.S. Environmental Protection Agency (USEPA). This document has been approved by USEPA, and is the final version of the document.

## 1.0 HUMAN HEALTH RISK ASSESSMENT OVERVIEW

In April 2004, the United States Environmental Protection Agency (USEPA) and the Respondents (Brown Inc., Ddalt Corp., Bulk Transport Corp., and Northern Indiana Public Service Company (NIPSCO)) signed an Administrative Order on Consent (AOC II) (Docket No. V-W-'04-C-784) to conduct a Remedial Investigation and Feasibility Study (RI/FS) at the Pines Area of Investigation, as set forth in Exhibit I to AOC II located in the environs of the Town of Pines, Indiana. The area to be investigated under the RI/FS will be referred to as the Pines Area of Investigation or just the Area of Investigation. The components of the RI/FS Work Plan are set out in AOC II (Section VII. 20) and the Statement of Work (SOW) (Task 2), which is provided as an attachment to AOC II. The Work Plan has been developed in seven volumes, which together provide the comprehensive approach and specific details for conducting the RI/FS for the Area of Investigation. These volumes are as follows:

- Volume 1 – Work Plan Overview
- Volume 2 – Field Sampling Plan (FSP)
- Volume 3 – Quality Assurance Project Plan (QAPP)
- Volume 3 – Health and Safety Plan (HASP)
- Volume 5 – Human Health Risk Assessment Work Plan (HHRA)
- Volume 6 – Ecological Risk Assessment Work Plan (ERA)
- Volume 7 – Quality Management Plan (QMP)

This HHRA Work Plan is a component (Volume 5) of the RI/FS Work Plan. The HHRA Work Plan has been prepared to follow the requirements in AOC II and the SOW, as well as to be compliant with the National Contingency Plan (NCP) (USEPA, 1990).

The purpose of the HHRA Work Plan is to develop the methods for evaluating human health risks using data collected as part of the RI/FS for the Pines Area of Investigation. It meets the requirements of AOC II and the SOW and is compliant with the National Contingency Plan (NCP) (USEPA, 1990).

The SOW provides at Section 5.1:

“Respondents shall conduct a human health risk assessment that focuses on the evaluation of current and future risks to persons coming into contact with on-site hazardous substances or constituents as well as risks to the nearby residential, recreational and industrial worker



populations from exposure to hazardous substances or constituents in groundwater, soils, sediments, surface water, air, and ingestion of contaminated organisms in nearby, impacted ecosystems. The human health risk assessment shall define central tendency and reasonable maximum estimates of exposure for current land use conditions and reasonable future land use conditions. The human health risk assessment shall use data from the Site and nearby areas to identify the constituents of potential concern (COPC), provide an estimate of how and to what extent human receptors might be exposed to COPCs, and provide an assessment of the health effects associated with these COPCs. The human health risk assessment shall assess potential human health risk if no cleanup action is taken at the Site.

“Respondents shall conduct the human health risk assessment in accordance with USEPA guidance including, at a minimum: “Risk Assessment Guidance for Superfund (RAGS), Volume I – Human Health Evaluation Manual (Part A),” Interim Final (EPA-540-1-89-002), OSWER Directive 9285.7-01A; December 1, 1989 [USEPA, 1989a] and “Risk Assessment Guidance for Superfund (RAGS), Volume I – Human Health Evaluation Manual (Part D, Standardized Planning Reporting, and Review of Superfund Risk Assessments),” Interim, (EPA 540-R-97-033), OSWER 9285.7-01D, January 1998 [USEPA, 1998a].”

The risk assessment shall also include the following elements:

- Hazard Identification. Available information on the constituents present will be reviewed to identify the major COPCs. COPCs will be identified based on established background levels and human health risk-based screening levels. Constituents with detected concentrations below established background levels and/or human health risk-based screening levels will not be identified as COPCs.
- Conceptual Exposure/Pathway Analysis.
- Characterization of the Area of Investigation and Potential Receptors.
- Exposure Assessment. As stated in the SOW, both central tendency and reasonable maximum estimates of exposure for current and reasonably foreseeable future land use conditions will be developed.
- Dose-Response Assessment.
- Risk Characterization.
- Identification of Limitations/Uncertainties.

The SOW states that, in addition to the guidance documents listed above, the HHRA will be conducted in accordance with guidance contained in the following Office of Solid Waste and Emergency Response (OSWER) directives:

1. Clarification to the 1994 Revised Interim Soil Lead Guidance for CERCLA [Comprehensive Environmental Response, Compensation and Liability Act] Sites and RCRA [Resource Conservation and Recovery Act] Corrective Action Facilities. OSWER Directive 9200.4-27. August 1998. (USEPA, 1998b);
2. USEPA Soil Screening Guidance: Technical Background Document. OSWER Directive 9355.4-17A. May 1, 1996 (USEPA, 1996b) and Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites. OSWER Directive 9355.4-24. March 2001. (USEPA, 2001);
3. Soil Screening Guidance: User's Guide. Publication 9355.4-23. April, 1996. (USEPA, 1996a);
4. Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities. OSWER Directive 9355.4-12. July 14, 1994. (USEPA, 1994a);
5. Guidance Manual for the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children. Publication 9285.7-15-1. February 1994 (USEPA, 1994b), and associated, clarifying, Short Sheets on IEUBK Model inputs, including, but not limited to, OSWER 9285.7-32 through 34, as listed on the OSWER lead internet site at [www.epa.gov/superfund/programs/lead/prods.htm](http://www.epa.gov/superfund/programs/lead/prods.htm);
6. Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children. Version 0.99D, NTIS PB94-501517, (USEPA, 1994b) or Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children. Windows version©. (USEPA, 2002a);
7. Risk Assessment Guidance for Superfund: Volume I – Human Health Evaluation Manual: (Part B, Development of Risk-based Preliminary Remediation Goals). Interim, OSWER Directive 9285.6-03. December, 1991. (USEPA, 1991c);
8. Human Health Evaluation Manual Supplemental Guidance: Standard Default Exposure Factors. OSWER Directive 9285.6-03, March 25, 1991. (USEPA, 1991a);
9. Exposure Factors Handbook (EFH), Volumes I, II, and III; August 1997. (EPA/600/P-95/002Fa, b, c) (USEPA, 1997a);
10. Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. OSWER 9655.0-30. April, 1991. (USEPA, 1991b); and
11. Land Use in the CERCLA Remedy Selection Process. OSWER 9355.7-04, 1995. (USEPA, 1995a).

The HHRA will evaluate potential human health effects using the four step paradigm as identified by the USEPA (USEPA, 1989a). The steps are:

- Data Evaluation and Hazard Identification
- Dose-Response Assessment
- Exposure Assessment
- Risk Characterization

## **1.1 Work Plan Organization**

The HHRA Work Plan is organized into the following sections:

- Area of Investigation Characterization and Conceptual Site Model – Section 2.0 of this Work Plan discusses the Area of Investigation and its environs, and presents a conceptual site model describing sources, potential migration pathways, and potentially impacted media.
- Hazard Identification – Section 3.0 of this Work Plan presents a discussion of how data collected from the Area of Investigation will be summarized, and a description of the process used for the selection of COPCs to be evaluated quantitatively in the risk assessment.
- Dose-Response Assessment – Section 4.0 of this Work Plan presents a discussion of the dose-response assessment process. The dose-response assessment evaluates the relationship between the magnitude of exposure (dose) and the potential for occurrence of specific health effects (response) for each COPC. Both potential carcinogenic and noncarcinogenic effects will be considered. The most current USEPA-verified dose-response values will be used when available.
- Exposure Assessment - Section 5.0 of this Work Plan presents a discussion of the exposure assessment process. The purpose of the exposure assessment is to provide a quantitative estimate of the magnitude and frequency of potential exposure to COPCs by a receptor. Potentially exposed receptor populations (referred to as receptors), and the pathways through which those populations may be exposed to COPCs are identified based on both physical characteristics and current and reasonably foreseeable future land uses. The extent of a receptor's exposure is estimated by constructing exposure scenarios that describe the potential pathways of exposure to COPCs and the activities and behaviors that might lead to contact with COPCs in the environment. Two exposure scenarios, the Reasonable Maximum Exposure (RME) and the Central Tendency Exposure (CTE) will be evaluated for each receptor. The RME scenario is intended to provide an upper-bound estimate of potential risk while the CTE is intended to provide a more typical or average estimate of potential risk.
- Risk Characterization – Section 6.0 of this Work Plan presents a discussion of the risk characterization process and uncertainties associated with the risk assessment process.

Risk characterization combines the results of the exposure assessment and the dose-response assessment to derive location-specific estimates of potentially carcinogenic and noncarcinogenic risks resulting from both current and reasonably foreseeable future potential human exposures to COPCs. The results of the risk characterization will be used to identify constituents of concern (COCs), which are the subset of those COPCs whose risks result in an exceedance of the target risk range of  $10^{-6}$  to  $10^{-4}$  for potential carcinogens and a target Hazard Index of 1 for noncarcinogens (that act on the same target organ) (USEPA, 1990; 1991b).

For each step of the human health risk assessment process described above, assumptions must be made due to a lack of absolute scientific knowledge. Some of the assumptions are supported by considerable scientific evidence, while others have less support. The assumptions that introduce the greatest amount of uncertainty in this risk assessment will be discussed in the Risk Characterization section of the HHRA report.

- Summary and Conclusions – Section 7.0 of the Work Plan notes that the HHRA report will summarize and discuss the conclusions of the HHRA.
- References - Section 8.0 presents the references used in this Work Plan.

## **2.0 AREA OF INVESTIGATION CHARACTERIZATION AND HHRA CONCEPTUAL SITE MODEL**

The HHRA conceptual site model (CSM) provides the basis for the development of the human health risk assessment. The role of the CSM in the HHRA is discussed in Section 2.1. To provide the context for the development of the HHRA CSM for the Pines Area of Investigation, Section 2.2 provides the historical background, and Section 2.3 provides a description of the Area of Investigation and environs. The HHRA CSM is then presented in Section 2.4.

### **2.1 Purpose of the HHRA CSM**

The CSM for human health is used to guide identification of appropriate exposure pathways and receptors for evaluation in the risk assessment. The purpose of the CSM is to identify 1) source areas, 2) potential migration pathways of constituents from source areas to environmental media where exposure can occur, and 3) potential human receptors. The CSM identifies potential sources, potential environmental release mechanisms, potential exposure pathways, potential exposure routes, and potential human receptors. Potentially complete exposure pathways are identified for consideration for further evaluation in the risk assessment. For an exposure pathway to be complete, the following conditions must exist (USEPA, 1989a):

1. A source and mechanism of constituent release to the environment;
2. An environmental transport medium (e.g., air, water, soil);
3. A point of potential receptor contact with the medium; and
4. A human exposure route at the contact point (e.g., inhalation, ingestion, dermal contact).

The first step in developing the CSM is the characterization of the setting and surrounding area. Current and reasonably foreseeable potential future land uses and potential receptors (i.e., residential or industrial receptors who may contact the impacted environmental media of interest) are then identified. Potential exposure scenarios identifying appropriate environmental media and exposure pathways for current and reasonably foreseeable potential future land uses and receptors are then developed. Those potential exposure pathways for which COPCs are identified and which are complete are evaluated quantitatively in the risk assessment. The CSM is meant to be a “living” model and the CSM for the Area of Investigation will be updated and modified as appropriate when additional data become available.

### **2.2 Historical Background**

Between 2000 and 2004, the Indiana Department of Environmental Management (IDEM) and USEPA responded to homeowners by conducting sampling of private water supply wells in a portion of the

Town of Pines. In some of these samples, boron and molybdenum were detected at concentrations above USEPA's Removal Action Levels (RALs) (USEPA, 1998c). These elevated concentrations in groundwater are suspected by the USEPA to be derived from coal combustion by-products (CCBs). CCBs have been disposed at a permitted Restricted Waste Facility known as Yard 520, and CCBs are suspected have been used as fill and road bed in areas within the Area of Investigation outside of Yard 520. Yard 520 is operated by Brown Inc., and most of the CCBs at Yard 520 were generated during combustion of coal at NIPSCO's Michigan City Generating Station.

To address the boron and molybdenum detections above the USEPA RALs, the Respondents agreed to extend the municipal water service from Michigan City to selected portions of the Town of Pines. This agreement was documented in an Administrative Order on Consent, referred to as AOC I. Additional sampling of other private wells indicated some concentrations near or exceeding USEPA RALs. To address this, the Respondents voluntarily approached the USEPA to discuss extending the municipal water service to a larger area, which incorporates the primary areas of interest, under an amendment to AOC I (AOC I amended). Figure 1 shows the Pines Area of Investigation, including areas previously connected to municipal water supply (North Area and South Area) and areas connected to municipal water supply under AOC I amended.

The objectives of the RI/FS, as outlined in the SOW attached to AOC II, are:

- (a) To determine the nature and extent of constituents in the Area of Investigation and any threat to the public health, welfare, or the environment caused by releases or threatened releases of constituents related to CCBs at or from the Area of Investigation, by conducting a Remedial Investigation.
- (b) To collect data necessary to adequately characterize, for the purpose of developing and evaluating effective remedial alternatives:
  - i) Whether the water service extension installed pursuant to AOC I and AOC I as amended is sufficiently protective of current and reasonable future drinking water use of groundwater in accordance with Federal, State, and local requirements;
  - ii) Whether there are significant human health risks at the Area of Investigation associated with exposure to CCBs; and
  - iii) Whether CCB-derived constituents may be causing unacceptable risks to ecological receptors.
- (c) To determine and evaluate alternatives for remedial action to prevent, mitigate, control or eliminate risks posed by any release or threatened release of constituents related to CCBs at or from the Area of Investigation, by conducting a Feasibility Study (FS).

Therefore, the purpose of the Remedial Investigation (RI) is to obtain the data necessary to appropriately evaluate current and potential reasonably foreseeable future risks to human health and ecological receptors based on actual location-specific conditions in the Pines Area of Investigation. The human health risk assessment will evaluate these risks. An ecological risk assessment will evaluate potential ecological risks (see Volume 6 of this RI/FS Work Plan). If risks are above the target risk range, the FS will evaluate the merits of alternative remedial technologies to address these risks. The target risk range is defined as  $10^{-6}$  to  $10^{-4}$  for potential carcinogens and a target Hazard Index of 1 for noncarcinogens (that act on the same target organ) (USEPA, 1990; 1991b). The media of interest for the RI/FS include CCBs (CCBs may be present alone or mixed with soil), and groundwater, surface water, and sediment that may have been impacted by CCB-derived constituents.

### **2.3 Pines Area of Investigation and Environs**

Figure 1 identifies the Pines Area of Investigation, as defined by AOC II. The area is located primarily in the Town of Pines, in Porter County, Indiana. The Area of Investigation is approximately 1,472 acres (2.3 square miles) in size and encompasses a variety of land types and land uses. The estimated population of the Town of Pines is approximately 800 (U.S. Census Bureau, 2004).

The Pines Area of Investigation is located immediately west of the city limits of Michigan City, Indiana, and about 1,500 feet south of the southern shore of Lake Michigan. The Indiana Dunes National Lakeshore (IDNL), managed by the National Park Service, is located between Lake Michigan and the Town of Pines. A small portion of the IDNL is included within the Area of Investigation for the RI/FS. Figure 2 is a U.S. Geological Society (USGS) topographic map showing specific features in the vicinity of the Area of Investigation.

The land use in the region varies from the relatively undeveloped areas of the IDNL, where the land has been preserved for recreational uses, to the highly developed industrial zones such as Burns Harbor and Michigan City. Industrial land use includes coal-fired power generating stations and fully-integrated steel mills. Selected areas have also been developed for residential housing, including the Town of Pines and Beverly Shores, which is located north of the Town of Pines along the shore of Lake Michigan.

The Area of Investigation contains residential areas, the majority of which are located on the south side of US Route 12. Additional residences are located mainly along Ardendale, Railroad Avenue, and Old Chicago Road. Each house historically may have had its own drinking water well or septic system or both. Figure 1 shows the portion of the Area of Investigation that is in the process of being provided municipal water service. Septic systems will continue to be used.

The Area of Investigation is bisected in the east-west direction by two major roadways, US Route 12 in the northern portion, and US Route 20 in the central portion. An east-west railroad also bisects the central portion of the Area of Investigation. A major utility corridor runs parallel and just to the north of

US Route 12. The IDNL comprises the portion of the Area of Investigation north of the utility corridor. Both residential and commercial establishments are located along US Route 12, and the area just south of US Route 12 consists mainly of single family homes, located mainly along the uplands of the dune-beach complex topography that characterizes this area of northern Indiana. South of the residential areas, and north of the railroad are the wetlands characteristic of the swale topography. These wetlands are now drained by the east and west branches of the man-made Brown Ditch, which was constructed to improve drainage and prevent flooding in the area. The confluence of the east and west branches of Brown Ditch is located approximately in the center of the Area of Investigation, where Brown Ditch then flows north into the IDNL. Within the IDNL the ditch takes a turn due east and flows into Kintzele Ditch, which then flows to Lake Michigan.

Yard 520, a permitted Restricted Waste Facility in the process of being closed under IDEM, is located in the western portion of the Area of Investigation, between US Route 20 to the north and Brown Ditch and the railroad to the south. Two no longer used dump sites, the Pines Landfill and the Lawrence Dump are located in the area to the south of Yard 520 and the railroad and north of Old Chicago Road.

In addition to the CCBs disposed of at Yard 520, suspected CCBs have also been observed in roadbed and other areas in certain portions of the Area of Investigation. Figure 3 depicts the information compiled about the potential locations of CCBs within the Area of Investigation, as presented in the Site Management Strategy (SMS) (ENSR, 2005a).

## **2.4 HHRA CSM**

A detailed preliminary characterization of the Area of Investigation and CSM of the geology and hydrogeology of the Area of Investigation are presented in Section 3.0 of the SMS (ENSR, 2005a).

Based on this information about the Area of Investigation, the HHRA CSM was developed to address what receptor populations might be exposed to CCB-derived constituents within the Area of Investigation, and how they might be exposed. Some receptor populations may be exposed to CCB-derived constituents by more than one pathway. Although there may be more than one potential exposure pathway, USEPA guidance (USEPA, 1989a) cautions that the first step is to identify reasonable exposure pathway combinations, and then to determine “whether it is likely that the same individuals would consistently face the reasonable maximum exposure by more than one pathway.” With this in mind, the CSM was developed by constructing potential exposure scenarios and identifying the hypothetical receptors to be used in evaluating these exposures. It is important to note that the exposure scenarios are constructed for hypothetical receptors who are assumed to be the most frequently exposed and the most sensitive receptors. The receptors are not intended to represent specific individuals.

Human receptor populations may potentially contact CCBs that are present at the ground surface due to their use as fill in the area as well as CCB-derived constituents that might have migrated from CCBs



into groundwater, surface water, or sediment. CCB-derived constituents may have migrated to these media in two ways: 1) the infiltration and percolation of rainwater through CCBs into the groundwater in the surficial aquifer, and potential subsequent transport to surface water; and 2) surface run-off and erosion of CCBs into surface water bodies. A surface water release could lead to increases in constituent concentrations in various aquatic media (i.e., surface water, sediments, and fish tissue).

Potential human receptor populations include residents, recreational visitors (i.e., who visit the Area of Investigation but do not reside in the area), and construction workers. Potential receptors and how they may contact CCBs are described below, and summarized on Figure 4.

- **Residents.** Residents (adults and children) may potentially contact surface CCBs directly via incidental ingestion and dermal contact. Additionally, residents may inhale CCB particulates entrained in dusts. Where groundwater is used as a source of drinking water, residents may ingest and contact CCB-derived constituents that have migrated into groundwater. The potential drinking water pathway is only complete for those residents who use groundwater as a drinking water source. Residential children who play in the local ditches may contact CCB-derived constituents (via incidental ingestion and dermal contact) that have potentially migrated into surface water or sediment.
- **Recreational Visitors.** Recreational visitors may be adults who fish in the local ditches or children who play in the local ditches. The ditches within the Area of Investigation are likely to contain fish, but it is not known at this time whether these fish are of an appropriate type or of sufficient abundance to support a recreational fishery. Until this information is obtained, it will be assumed that consumption of fish containing CCB-derived constituents is a potentially complete exposure pathway. Recreational fishers and recreational children may contact CCB-derived constituents (via incidental ingestion and/or dermal contact) that have potentially migrated to surface water or sediment. Recreational visitors may inhale CCB particulates entrained in dusts.
- **Construction Workers.** Construction workers may potentially contact surface and subsurface CCBs directly via incidental ingestion and dermal contact. Additionally, construction workers may inhale CCB particulates entrained in dusts. Construction workers may also directly contact CCB-derived constituents in groundwater via dermal contact if groundwater is encountered during an excavation.

## **2.5 Phased Approach**

As discussed in the Work Plan Overview (Volume 1 of this RI/FS Work Plan), a phased approach will be used to evaluate potential risks related to direct contact with CCBs. Data from the first phase will include analyses of samples collected as part of the Municipal Water Service Extension (MWSE) Sampling and Analysis Plan (SAP) (ENSR, 2004) and the Yard 520 SAP (ENSR, 2005b). Using these data, a screening level risk assessment for CCBs will be conducted. This will include a comparison to

background and consideration of arsenic bioavailability (see Section 4.2 of this Work Plan). An evaluation of chemical and physical CCB data by location may be used to determine if there are subsets of CCBs with significantly differing characteristics. If there are significant differences, the preliminary screening level risk assessment would be conducted on these subpopulations separately. The results will be used to determine whether further investigation or evaluation of CCBs for human health risk is warranted. This step will help to focus what areas and what data warrant further, more detailed and more location-specific evaluation. If the total preliminary screening level risk does not exceed target risk levels as defined in Section 1.1.1, or the constituent concentrations are consistent with background, no further evaluation is necessary, including no need to further delineate CCB emplacement in the Area of Investigation. If the screening level risk assessment indicates there is a need for further evaluation, additional data may be collected during an additional phase of work to further delineate the location of CCBs.

### 3.0 HAZARD IDENTIFICATION

The purpose of the hazard identification process is two-fold: 1) to evaluate the nature and extent of release of CCB-derived constituents present at the Area of Investigation; and 2) to select a subset of constituents identified as COPCs for quantitative evaluation in the risk assessment. This step of the risk assessment will involve compiling and summarizing the RI/FS data relevant to the risk assessment, and selecting COPCs based on a series of screening steps.

#### 3.1 Types of Data that may be Collected

The RI/FS has been developed to address the potential media and migration pathways identified in Section 2.0. Sampling to be conducted in support of the RI/FS may include the following:

- Surface CCBs (0-6 inches below ground surface (bgs));
- Subsurface CCBs (greater than 6 inches bgs);
- Groundwater (including from private wells);
- Sediment; and
- Surface water.

Private drinking water wells will be sampled as part of the RI. Data obtained in the RI will be used in the HHRA only if the following conditions are met:

1. The screened interval is documented in drillers' records and/or the Indiana Department of Natural Resources (IDNR) database;
2. The well is screened in the surficial aquifer;
3. The water quality in the well does not appear to be impacted by septic systems or other sources; and
4. Only CCB-derived constituents detected in the wells will be evaluated.

Where private well data collected in the RI are determined to be appropriate for use in the HHRA, the data will be evaluated in combination with groundwater data collected from monitoring wells.

If the fish tissue pathway is determined to be complete, fish tissue samples may be collected; or fish tissue concentrations may be estimated from surface water concentrations. A potential human health exposure pathway is the inhalation of particulates derived from CCBs either at the surface or disturbed in an excavation. Due to the numerous potential background sources of CCB-related constituents in

air, and the natural hourly, daily and seasonal fluctuations in air quality, air concentrations of COPCs will be predicted using models (see Section 5.5.1).

Analytical data for use in the RI/FS from background or reference locations will be available for the following media:

- Surface soils;
- Subsurface soils;
- Groundwater;
- Sediment; and
- Surface water.

Fish tissue samples will be collected from reference areas only if samples are also collected from the Area of Investigation.

Investigation and/or COPC screening at the Area of Investigation may limit which of the above media need to be evaluated quantitatively in the HHRA (e.g., if no COPCs are identified for a particular medium, then that medium will not be evaluated in the quantitative HHRA). However, this Work Plan begins with the assumption that all media will be evaluated quantitatively in the HHRA. These are: CCBs, surface water, sediments, groundwater, fish tissue, and air.

The RI/FS FSP identifies the suites of analytes for each medium. The field sampling program is discussed in detail in Volume 2 of the RI/FS Work Plan.

### **3.2 Data Compilation and Summary Statistics**

All analytical data collected in support of the RI/FS will be compiled and tabulated in a database for statistical analysis. Tables of summary statistics will be developed, and will present for each constituent the minimum and maximum detected values, the arithmetic mean, and the frequency of detection.

Exposure areas may be identified for the human health risk assessment based on the results of the field sampling and other investigation data. The analytical results may indicate distinct areas that should be evaluated separately based on the types of material identified or types of exposures that may reasonably occur. If this is the case, separate summary statistics will be calculated for each area. For constituents selected for further analysis in the HHRA, the 95% upper confidence limit of the mean (UCL) will also be calculated (further discussed in Section 5.5.1).

The steps used to summarize the data are as follows:

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Treatment of Duplicates: Data for samples and their field duplicates will be averaged before summary statistics are calculated, such that a sample and its duplicate are treated as one sample for calculation of summary statistics (including maximum detection and frequency of detection).

Treatment of Non-Detects:

- Summary statistics will not be calculated for constituents that are not detected in a particular sample grouping. For any grouping of samples for which there is at least one detected value of a particular constituent, summary statistics will be calculated.
- If constituents are detected in some samples and not in others in a particular area/medium, an appropriate statistical technique for dealing with non-detected results will be determined based on USEPA guidance for calculating exposure point concentrations (USEPA, 2002b). The guidance presents three methods for handling non-detects:
  1. Simple substitution. In this method, a constant value or fraction of the detection limit (i.e.,  $\frac{1}{2}$  detection limit) is used as a proxy concentration.
  2. Bounding methods. This method is used to determine the upper and lower bounds of the UCL based on the full range of possible values for the detection limit, and is not based on the distribution of the data. If bounding indicates that the effects of the non-detects are negligible, no further analysis is required.
  3. Distributional methods. This method relies on the assumption that the shape of the distribution of the non-detects is similar to that of the detected concentrations, and derives proxy concentrations based on that distribution.

The appropriate method for handling non-detects will be determined based on the analytical data in each sample grouping. The method may be one of the three listed above. However, if none of these methods are appropriate for the analytical data, an alternative method may be used.

- Frequency of Detection: The frequency of detection will be reported as a ratio and a percentage, and is based on the number of samples reported as detected for a specific constituent and the number of samples used to calculate statistics. The number of samples used to calculate statistics reflects the treatment of non-detects described above.

Minimum Detected Concentration: This is the minimum detected concentration for each constituent/area/medium combination, after duplicates have been averaged.

Maximum Detected Concentration: This is the maximum detected concentration for each constituent/area/medium combination, after duplicates have been averaged.

Mean (Average) Concentration: This is the arithmetic mean concentration for each constituent/area/medium combination, after duplicates have been averaged and non-detects have been evaluated. For groundwater, results from multiple sampling phases will be averaged for each well prior to calculating the mean concentration for each constituent.

### **3.3 Selection of Constituents of Potential Concern**

COPCs are a subset of the complete set of constituents detected in media in the Area of Investigation that are carried through the quantitative risk assessment process. Selection of COPCs focuses the analysis on the most likely risk “drivers.” As stated in USEPA guidance (USEPA, 1993a):

“Most risk assessments are dominated by a few compounds and a few routes of exposure. Inclusion of all detected compounds at a site in the risk assessment has minimal influence on the total risk. Moreover, quantitative risk calculations using data from environmental media that may contain compounds present at concentrations too low to adversely affect public health have no effect on the overall risk estimate for the site. The use of a toxicity screen allows the risk assessment to focus on the compounds and media that may make significant contributions to overall risk.”

Therefore, COPCs will be identified by comparing constituent-specific analytical data for environmental media to appropriate screening levels and conducting a quantitative risk assessment for those constituents detected in an environmental medium in excess of the screening levels described below. Several factors are typically considered in identifying COPCs, including background, frequency of detection, and toxicity, including essential nutrient status. Risk calculations will be conducted for the COPCs identified in this step.

AOC II calls for the evaluation of COPCs derived directly from CCBs. Constituents such as boron and molybdenum may be present in the Area of Investigation from multiple sources. To the extent practical, only concentrations of COPCs derived from CCBs will be evaluated in the HHRA.

The steps to be used to identify COPCs are presented below. The steps will be conducted in sequential order, such that a constituent that meets the requirements of a given step will be eliminated as a COPC and will not be evaluated in subsequent steps.

#### **3.3.1 Frequency of Detection**

A frequency of detection screen will be conducted on each medium (e.g., surface water, groundwater, etc.). Constituents that are detected in fewer than 5% of samples, provided at least 20 samples are available, generally will not be identified as COPCs. However, such a constituent may be retained as a COPC based on professional judgment, considering factors such as the presence of a hotspot and whether it is a CCB-derived constituent.

### **3.3.2 Comparison to Applicable Standards and/or Screening Levels**

A risk-based screen will be performed to identify CCB-derived COPCs in each medium. The methods and screening level sources for each medium are described below. Either the maximum detected concentration from the Area of Investigation, or another appropriate statistical value (see Section 5.5.1) will be used in the comparisons.

#### **CCBs**

USEPA Region 9 Preliminary Remediation Goals (PRGs) (USEPA, 2004b) will be used to identify COPCs in CCBs potentially present in soil and sediment. PRGs are risk-based concentrations in soil corresponding to a cancer risk level of  $1 \times 10^{-6}$  and a hazard index of one. PRGs for residential soil assume daily contact by an adult and a child and assume incidental ingestion, dermal contact, and inhalation of soil derived dusts and vapors. PRGs for industrial soil assume contact for 250 days per year by an occupational adult and assume incidental ingestion, dermal contact, and inhalation of soil derived dusts and vapors. PRGs are not intended to represent “de facto” cleanup standards but rather are screening levels that help determine whether further evaluation is necessary for a particular constituent at a particular location (USEPA, 2004b).

Residential soil PRGs will be used to identify COPCs for the residential and recreational scenarios. Industrial soil PRGs will be used to identify COPCs for the construction worker scenario.

If radionuclides are detected in CCBs, COPCs for the residential and recreational scenarios will be identified using residential soil Radionuclide Toxicity and PRGs for Superfund, available from the following web-site: <http://epa-prgs.ornl.gov/radionuclides/> (USEPA, 2004f). COPCs for the construction worker scenario will be identified using outdoor worker soil PRGs available from the same source.

If no PRG is available, a value may be assigned to evaluate the constituent using a PRG from a structurally similar constituent.

#### **Groundwater and Surface Water**

The published USEPA RALs (USEPA, 1998c) have been used by USEPA in the area of the Town of Pines as precautionary levels to determine whether bottled water should be offered to residents on a temporary basis. In addition, the RALs have been used by USEPA as the basis for requiring an RI/FS for the Pines Area of Investigation. RALs are to be used as one factor in determining whether to provide interim alternate water supplies under Superfund removal authority. The USEPA RAL guidance notes that published numeric RALs “do not in any way restrict the flexibility to develop and apply site-specific RALs” (USEPA, 1998c).

RALs are not generally used in the selection of COPCs for a risk assessment. They will be used to select COPCs for groundwater for this risk assessment; however, they will not be the primary source. In some cases RALs are based on out-dated toxicity data, and more current information is available. The general hierarchy of screening levels for selecting COPCs in groundwater will therefore be as follows:

1. USEPA Primary Maximum Contaminant Levels (MCLs) (USEPA, 2004c)
2. USEPA RALs (USEPA, 1998c)
3. USEPA PRGs for tapwater (USEPA, 2004b)

If no screening level is available from any of the above sources, a value may be assigned to evaluate the constituent using a PRG from a structurally similar constituent.

The COPCs in groundwater for the RI/FS identified to date are boron and molybdenum, because they have been detected in some samples above the USEPA RALs (USEPA, 1998c).

The potential exposure pathway to COPCs in surface water is via dermal contact (see Section 5.2.2). There are no published screening levels for this potential exposure pathway. Therefore, COPCs in surface water will conservatively be selected using the same process noted above for groundwater. All the groundwater screening levels are based on a drinking water scenario and therefore are protective of potential recreational dermal exposures.

### **Fish Tissue**

Fish tissue data (modeled or measured) will be compared to the USEPA Region 3 Risk-Based Concentrations (RBCs) for fish (USEPA, 2004d).

#### **3.3.3 Comparison to Background**

Upgradient and other background samples collected in the vicinity of the Area of Investigation will provide information on levels of constituents typical for various media in the local area. Area of Investigation conditions will be compared to local background conditions. If Area of Investigation concentrations of constituents are representative of or consistent with background concentrations, they will not be included in risk calculations. Background comparisons will be conducted for each medium using Area of Investigation-specific background data. The background comparison will be conducted only for constituents identified above with concentrations above screening levels. The background comparison will be conducted in accordance with USEPA guidance (USEPA, 2002c). Figure 5 presents the method for comparing the background concentrations with the Area of Investigation concentrations. Handling of non-detects, testing for normality, and hypothesis testing are discussed below.



### **Treatment of Non-Detects**

Inclusion of non-detect results in the statistical analysis can create bias. With greater numbers of non-detect results, the bias becomes greater. When the frequency of detection is low, the statistical analysis will provide more information about the analytical detection limits than about actual concentrations. Therefore, a background comparison will not be conducted using this methodology for any constituent with a frequency of detection less than 50% in either the background or Area of Investigation data sets. Nonparametric methods (see below) will be used to compare data sets with a frequency of detection between 50% and 80%. Parametric or nonparametric methods, as applicable, will be used to evaluate data sets with frequency of detection equal to or greater than 80%.

Because the data sets that include a large percentage of non-detects will be excluded, the non-detect values in the remaining data sets will be assumed not to introduce significant statistical bias. Therefore, all non-detect values will be replaced with  $\frac{1}{2}$  the value of the sample quantitation limit (SQL) for the purposes of calculating the statistics. Where  $\frac{1}{2}$  the SQL is greater than the highest detected concentrations, the sample results for the non-detect will be eliminated from the analysis.

### **Tests for Normality**

For data sets with a frequency of detection equal to or greater than 80%, each constituent in each data set (i.e., background and non-background data sets) will be tested to determine whether the data are normally or lognormally distributed. The Shapiro Wilk test (W-statistic) will be used for this determination ( $\alpha=0.10$ ). To evaluate a lognormal distribution, the data will be transformed by calculating the natural logarithm of each concentration. If both untransformed and log-transformed data are normally distributed, the one with the better fit to normality (greater W) will be used.

### **Parametric Comparison of Datasets**

For any individual constituent where frequency of detection is greater than 80%, and both the data distributions (i.e., background and non-background) are normal or lognormal, Student's t-test ( $\alpha=0.10$ ) will be used to compare the datasets. The t-test for unequal variance will be used. For the lognormally distributed data sets, all calculations will be performed on the log-transformed data.

### **Non-Parametric Comparison of Datasets**

For any individual constituent where the frequency of detection is less than 80% but greater than 50%, if the data distributions (background and non-background) are neither normally nor lognormally distributed, or if the distributions are mixed, then a non-parametric comparison will be necessary. The Wilcoxon Rank-Sum Test (also known as the Mann-Whitney U Test) will be used for the non-parametric comparison ( $\alpha=0.10$ ).

## **Hypothesis Testing**

Data will be evaluated using statistical background Test Form 2 (USEPA, 2002c). Background Test Form 2 requires a strict burden of proof by selecting the null hypothesis that the constituent concentration exceeds background by more than some defined difference S. This approach favors the protection of the environment (USEPA, 2002c). A difference (S) of one standard deviation will be considered to provide a reasonable ability to distinguish differences between data sets.

If background data are normally or lognormally distributed, and frequency of detection is at least 80%, S will be calculated as one standard deviation of the background data set, with the standard deviation calculated in log-space for lognormally distributed data. If the background data are neither normally nor lognormally distributed, or if the frequency of detection is greater than 50% but less than 80%, a percentile value will be calculated equivalent to the mean plus one standard deviation in a normally distributed data set (84.13<sup>th</sup> percentile). The S for nonparametric tests will be determined as the difference between the 84.13<sup>th</sup> percentile and the median (50<sup>th</sup> percentile) of the background data set. A statistically-based difference was selected so that the difference is based on the statistical properties of the data set. Where variances are large, a larger difference will be needed to distinguish data sets. In addition, this approach is readily applied for either transformed or un-transformed data.

Figure 5 provides a graphical depiction of the test selection criteria. The specific hypotheses to be used in the HHRA are as stated in Test Form 2 (USEPA, 2002c):

$H_0$ : The mean of the concentration in the Area of Investigation (A) data set is greater than the mean of the background data (B) set by at least S where, S = one standard deviation ( $u_A \geq u_B + S$ ).

$H_A$ : The mean of the concentration in the Area of Investigation (A) data set does not exceed the mean of the background (B) data set by S ( $u_A < u_B + S$ ).

If the null hypothesis  $H_0$  is rejected, it can be concluded with statistical significance that the mean of the Area of Investigation data set is not significantly greater than the mean of the background data set, or that, in general, Area of Investigation concentrations are similar to background concentrations. If the null hypothesis is not rejected, it will be assumed that the mean from the Area of Investigation data set may be greater than the mean of the background data set, although this is not a statistically significant conclusion. This hypothesis will be tested at the 0.10 level of significance ( $\alpha = 0.10$ ).

## **Evaluation of Power**

Because the null hypothesis is structured to assume concentrations are greater than background, it is important to evaluate the power of the test. The power represents the ability of the test to reject the null hypothesis; specifically, are there enough samples to make it theoretically possible to reject the null hypothesis? The goal is try to achieve a power of 80-90% for the statistical comparisons. Because of

the structure of the null hypothesis (Test Form 2), insufficient power may result in a Type II error, the incorrect acceptance of the alternative hypothesis, that the site data are greater than the background data. The power for each parametric comparison will be calculated and reported with the results. If power is low, this will be addressed in the uncertainty evaluation.

In addition to evaluating concentrations of constituents in upgradient and other background samples, literature sources will be reviewed for regional background levels of constituents in environmental media.

#### **3.3.4 Essential Nutrients**

Essential nutrients are defined as calcium, iron, magnesium, sodium, and potassium (USEPA, 1989a). According to USEPA (1989a) essential nutrients do not need to be evaluated in a quantitative HHRA when they are present at low concentrations (i.e., only slightly elevated above background levels) and toxic only at very high doses. Screening values are not available for calcium, magnesium, sodium, or potassium (USEPA, 2004b, USEPA, 2004c, USEPA, 2004d, USEPA, 1998c). PRGs are available for iron for soil and tapwater (USEPA, 2004b). Therefore, iron concentrations will be compared to PRGs as described in Section 3.3.2. If iron concentrations are greater than PRGs, iron will be evaluated in the background comparison described in Section 3.3.3. Magnesium, sodium, and potassium will also be evaluated in the background comparison. Essential nutrients that are not eliminated based on the PRG comparison or the background comparison will be evaluated further using a weight of evidence approach to determine if they should be included in the HHRA.

#### **3.3.5 Summary**

Constituents will be screened based on frequency of detection, background levels, and the screening levels described above. The published screening levels are periodically updated by USEPA. The most current values available will be used in the selection of COPCs. The screening levels as of September 2005 are shown in Appendix A. If no COPCs are identified for a medium, that medium will not be evaluated quantitatively in the HHRA.

Tables presenting the results of each screening step will be presented in the risk assessment report. The final list of COPCs for inclusion in the risk assessment will also be presented in the risk assessment and those COPCs will be included in all subsequent risk calculations.

It is important to note that the screening levels are to be used to identify COPCs only, and that a full assessment of applicable or relevant and appropriate requirements (ARARs), such as primary MCLs, and guidance “to be considered” (TBCs), such as the Indiana Risk Integrated System of Closure (RISC) (IDEM, 2001), will be completed before preliminary and final remedial action objectives are selected.

### **3.4 Data Quality Levels**

The screening levels identified in Section 3.3.3.2 have been used to develop the data quality levels (DQLs) to be used to identify appropriate practical quantitation limits (PQLs) for laboratory methods for the analytical program. The DQLs and PQLs are discussed in greater detail in the QAPP for the Area of Investigation (see Volume 3 of the RI/FS Work Plan).

## 4.0 DOSE-RESPONSE ASSESSMENT

The purpose of the dose-response assessment is to identify the types of adverse health effects a constituent may potentially cause, and to define the relationship between the dose of a constituent and the likelihood of an adverse effect (response).

Adverse effects are defined by USEPA as potentially carcinogenic or noncarcinogenic (i.e., potential effects other than cancer). The USEPA has defined the dose-response values for potentially carcinogenic effects as Cancer Slope Factors (CSFs) or Unit Risk Factors (URFs), and dose-response values for noncarcinogenic effects as Reference Doses (RfDs) or Reference Concentrations (RfCs). Subchronic RfDs and RfCs apply to substantially less than lifetime exposures (USEPA, 1989a), generally exposures less than seven years in duration (i.e., 1/10<sup>th</sup> of the average lifetime of 70 years). Chronic RfDs and RfCs apply to exposures greater than seven years duration.

The USEPA's guidance for sources of human health dose-response values in risk assessment will be followed in selecting dose-response values (USEPA, 2003). Sources of published dose-response values that will be used in the HHRA include USEPA's Integrated Risk Information System (IRIS) (USEPA, 2005), the USEPA National Center for Environmental Assessment (NCEA) in Cincinnati, Ohio, and the Health Effects Assessment Summary Tables (HEAST) (USEPA, 1997b).

Dose-response values used in the risk assessment will be presented in tabular format. For each constituent the table will present the Chemical Abstracts Service (CAS) registry number, dose-response value, source, study animal, study method, and where appropriate, target organ, critical effect, uncertainty factors, and confidence level.

Dose-response values are available for oral and inhalation exposures. Oral dose-response values will be used to evaluate dermal exposures, provided appropriate dermal absorption values are available. COPCs will be evaluated quantitatively for the dermal exposure pathway. For inhalation pathways, reference concentrations (in units of mg/m<sup>3</sup>) will be converted to reference doses (in units of mg/kg-day) for calculating risk for constituents with systemic effects. For constituents with direct acting effects by the inhalation route of exposure, the inhalation and ingestion/dermal pathways will be evaluated separately.

Additional information is presented below for several constituents or constituent groups.

### 4.1 Lead

Because of the uncertainties in the dose-response relationship between exposure to lead and biological effects, it is unclear whether the noncarcinogenic effects of lead exhibit a threshold response. Therefore, an RfD for lead is not available. Although USEPA has classified lead as a B2

(probable human) carcinogen, a CSF has not been developed yet. Therefore, potential exposures to lead cannot be evaluated using the traditional methods of risk assessment. However, the USEPA has developed an Integrated Exposure Uptake Biokinetic (IEUBK) model that correlates lead levels in the environment to blood lead levels in children (USEPA, 2002a). Because children are more sensitive to the effects of lead than adults, only children will be evaluated for the residential and recreational scenarios for potential exposures to lead. If lead is identified as a COPC in CCBs for the construction worker, the USEPA Adult Lead Model will be used (USEPA, 1996c). If lead is identified as a COPC in groundwater for the construction worker, the Bower's Model (Bowers et al., 1994), which assesses exposure to lead in water for adults, will be used. Lead is not expected to bioaccumulate into fish tissue and will therefore not be evaluated in the fish ingestion pathway.

#### **4.2 Arsenic Bioavailability**

Arsenic might be a COPC for the CCB direct contact pathway. Bioavailability is an important consideration for arsenic exposure. Bioavailability is a measure of how much of a constituent may be absorbed upon exposure. It is only the absorbed fraction that can then potentially result in an effect. Due to chemical and physical properties, especially of solid matrices, not all arsenic contacted will actually be absorbed. Bioavailability of arsenic in solid matrices (e.g., soil) can range from as low as 0.5% to as high as 90%.

A variety of in vitro and in vivo bioavailability tests are available for arsenic. USEPA Region 6 has developed an in vivo assay for measuring the bioavailability of arsenic. This assay has been used by USEPA Region 1 (USEPA, 2004a) to determine the relative bioavailability of arsenic in river system sediments. Estimates of the relative bioavailability of arsenic in sediment (compared to arsenic in drinking water, the exposure upon which the dose-response value is based) in the study ranged from 32% to 56%. If the risk assessment results indicate that potential risks from arsenic are above target risk levels, determining the bioavailability of arsenic may be an important component of the risk assessment process. In the event a bioavailability study for arsenic is included in the HHRA, a protocol for conducting such a study is presented in Appendix B.

#### **4.3 PCDDs and PCDFs**

The potential carcinogenic effects associated with exposure to polychlorinated dibenzodioxin (PCDD) and polychlorinated dibenzofuran (PCDF) congeners in environmental media will be assessed in accordance with the approach developed by USEPA (1989b) or final guidance available at the time the risk assessment is conducted. Risks will be calculated for 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD) and the PCDD/PCDF congeners using the cancer slope factor for 2,3,7,8-TCDD listed in HEAST (USEPA, 1997b) and using toxic equivalency factors (TEFs). TEFs are fractions that equate the potential toxicity of each congener to that of 2,3,7,8-TCDD. The World Health Organization (WHO) (Van den Berg et al., 1998) has assigned a TEF to each of the PCDD/PCDF congeners. The TEFs are listed in Table 1. The concentration for each PCDD/PCDF congener will be multiplied by its TEF,

resulting in a TCDD toxic equivalence concentration (TCDD-TEQ). The TCDD-TEQ values for each of the congeners will then be added together to derive a TCDD-TEQ for each sample. This TCDD-TEQ will be used to calculate summary statistics as described in Section 3.2 and exposure point concentrations as described in Section 5.5.1. The cancer slope factor for 2,3,7,8-TCDD will then be used to calculate potential carcinogenic risks resulting from potential exposure to 2,3,7,8-TCDD, and the PCDD/PCDF congeners.

#### **4.4 Polycyclic Aromatic Hydrocarbons**

Polycyclic aromatic hydrocarbons (PAHs) are products of incomplete combustion and may therefore be components of CCBs. Because there are also many sources of PAHs in the environment that are not associated with CCBs, background samples will be collected for comparison with CCB samples. Only PAHs above both background and risk-based screening levels will be evaluated in the HHRA.

Seven PAHs have been identified by USEPA as potentially carcinogenic (as listed in Table 2). USEPA (2005) has developed an oral CSF for only one of these seven, benzo(a)pyrene. The potential carcinogenic effects associated with exposure to PAHs in environmental media will be assessed in accordance with the toxicity equivalence approach developed by USEPA (1993b). CSFs for other PAHs will be calculated by adjusting the benzo(a)pyrene CSF with the relative potency factor (USEPA, 1993b) that are specific for each of the PAHs. Relative potency factors are the same in concept as TEFs, i.e., they are fractions that equate the potential toxicity of each potentially carcinogenic PAH to that of benzo(a)pyrene. The relative potency factors for the potentially carcinogenic PAHs are listed in Table 2.

Additionally, potentially carcinogenic PAHs will be evaluated for noncarcinogenic effects. However, RfDs are not available for the potentially carcinogenic PAHs. Therefore, surrogate RfDs will be applied based on structural similarities between the potentially carcinogenic PAHs and the noncarcinogenic PAHs.

#### **4.5 Radionuclides**

Under CERCLA, radionuclide risk assessment is governed by the risk range for carcinogens established in the NCP when ARARs are not available or sufficiently protective (USEPA, 1997c). Therefore, all potential risks from radionuclides will be evaluated in the context of the risk range, since the Nuclear Regulatory Commission (NRC) dose levels are not ARARs.

If radionuclides are selected as COPCs, either the USEPA website (<http://epa-prgs.ornl.gov/radionuclides/>) (USEPA, 2004f) or other appropriate methods as available will be used to calculate potential risks. The only radionuclide identified by USEPA which may pose a potential risk via noncarcinogenic effects is uranium. Therefore, should uranium be selected as a COPC, uranium hazards will also be calculated in the HHRA along with the non-radionuclide COPCs.

## **5.0 EXPOSURE ASSESSMENT**

The purpose of the exposure assessment is to predict the magnitude and frequency of potential human exposure to each of the COPCs retained for quantitative evaluation in the HHRA. The first step in the exposure assessment process is the characterization of the setting of the location and surrounding area. Current and reasonably foreseeable potential future uses and potential receptor populations (i.e., those who may contact the impacted environmental media of interest) are then identified. Potential exposure scenarios appropriate to current and reasonably foreseeable potential future uses and receptors are then developed. Those potential exposure pathways for which COPCs are identified and are judged to be complete will be evaluated quantitatively in the risk assessment. Reasonable maximum exposure (RME) assumptions, and central tendency exposure (CTE) assumptions based on appropriate USEPA guidance, will be employed in the quantitative risk assessment.

### **5.1 Identification of Potential Exposure Scenarios**

Exposure scenarios are developed on the basis of the HHRA CSM. The HHRA CSM for the Area of Investigation as a whole was presented in detail in the SMS document (ENSR, 2005a). The specific components of the HHRA CSM were summarized in Section 2.0 and depicted on Figure 4. The CSM was used to develop the potential exposure scenarios identified below.

#### **5.1.1 Groundwater**

The Area of Investigation contains residential areas. Each house either has its own private drinking water well or is connected to the municipal water system. Currently, there are two groups of residents with respect to potential groundwater exposures:

1. Those within the area of municipal water supply service.
2. Those outside the area of municipal water supply service.

CCB-derived constituents may have potentially migrated from CCBs into groundwater. Residents outside the area of the municipal water service may be exposed to CCB-derived constituents in groundwater via ingestion and via dermal contact while bathing. Construction workers could potentially be exposed to CCB-derived constituents in groundwater via dermal contact if water is encountered during excavation.

Because the shallow aquifer may be the only aquifer potentially affected by CCBs, once that determination has been made, only the shallow groundwater aquifer will be evaluated in the HHRA.



### **5.1.2 CCBs**

The following describes potential routes of exposure to CCBs. Receptors may potentially contact CCBs that have been used as fill in the area. Ingestion, dermal contact, and inhalation of CCB-derived dusts are potential exposure pathways and will be evaluated in the HHRA for CCB-derived constituents that are identified as COPCs. In general, the dermal contact pathway is negligible for metals. Therefore, dermal contact with metals in CCBs may be an incomplete pathway. Residents and visitors may potentially be exposed to CCBs present at the ground surface, while construction workers may potentially be exposed to CCBs present at the surface and in the subsurface.

As noted in Section 2.5, a phased approach will be used to evaluate potential direct contact with CCBs. If the screening level risk assessment indicates the need for further evaluation of CCBs in the baseline risk assessment, additional data may be collected to determine more specifically where in the Area of Investigation contact with CCBs is possible and under which exposure scenarios. Direct contact with CCBs would be evaluated only for those areas where CCBs are found to be present.

### **5.1.3 Sediment, Surface Water, and Fish Tissue**

CCB-derived constituents may also have migrated from CCBs into surface water and sediment either directly or via groundwater discharge. Recreational users of local ditches may therefore be exposed to CCB-derived constituents in surface water and sediment via incidental ingestion and/or dermal contact. According to USEPA (2004e), "Sediments which are consistently covered by considerable amounts of water are likely to wash off before the individual reaches the shore." The guidance therefore recommends the use of sediment samples which are near shore. Where possible, sediment samples will be collected from shallow portions of the ditches in order to represent "near-shore" sediment. However, portions of the ditches may be deep and may not contain shallow portions. In these cases, it will be assumed that sediment is not available for human contact.

Additionally, it is possible that fish contain CCB-derived constituents. Therefore, recreational fishers may potentially be exposed to CCB-derived constituents via fish tissue ingestion.

Table 3 shows the receptor populations that will be quantitatively evaluated in the HHRA, and indicates the media and pathways to which each receptor is assumed to be exposed.

## **5.2 Receptor Identification**

The potential receptor populations to be evaluated quantitatively in the HHRA are described below. Pathways to be evaluated are presented in Figure 4 and in Table 3. Exposure parameters have been developed for both RME and CTE scenarios, and are presented in Tables 4 through 7. Exposure assumptions are discussed in more detail in Section 5.3.

### **5.2.1 Resident (Adult and Child)**

Table 4 presents the exposure assumptions for a residential adult and child receptor for both RME and CTE exposures. Because of the differences in activity patterns and sensitivity to potential constituent exposures, two age groups for the resident receptor will be evaluated: the child (age 0 to 6 years, 15 kg body weight) and the adult resident (70 kg body weight) (USEPA, 1991a). The child's lower body weight, combined with a high intake rate for soil exposures results in a higher dose per kilogram of body weight than for other age groups. This receptor is then the most sensitive to the noncarcinogenic health effects of constituents and is, therefore, the target receptor for the noncarcinogenic analysis. Because carcinogenic effects are assumed to be additive over a lifetime, it is more conservative to evaluate potentially carcinogenic effects of COPCs over the period of residence. USEPA (1997a) lists 30 years as the 95<sup>th</sup> percentile value for residence time. This estimate was derived from three studies:

- U.S. Census Bureau, 1993 (housing survey), as cited in U.S. EPA, 1997a;
- Israeli and Nelson, 1992, as cited in U.S. EPA 1997a; and
- Johnson and Capel, 1993, as cited in U.S. EPA, 1997a.

According to the Exposure Factors Handbook (EFH) (USEPA, 1997a), while information provided by the U.S. Census Bureau does provide information regarding population mobility, it is difficult to determine the average residence time in a home or apartment because the surveys are not designed to follow individual families through time. Therefore, the three listed sources, which each used a unique approach to quantify residence time, were used to derive the estimates provided in the EFH. According to the EFH, the studies provide residence time estimates that are similar. Therefore, the 95<sup>th</sup> percentile estimate of 30 years will be used in the HHRA as a conservative estimate of the time a hypothetical receptor may live in the same residence location. The resident, as both child and adult, is thus evaluated for potential carcinogenic effects of COPCs over a 30-year residency period.

The resident receptor is assumed to be exposed to COPCs in surface CCBs where present via incidental ingestion and dermal contact and to COPCs in CCBs where present in outdoor dust via inhalation. Depending on the locations of surface CCBs within the Area of Investigation, the exposure frequency listed in Table 4 may be adjusted to accurately reflect potential exposures. Residents who are outside that area of municipal water service are assumed to be exposed to COPCs via ingestion of drinking water and via dermal contact while bathing. The residential child is assumed to play in local ditches, and is therefore assumed to be exposed to COPCs in surface water and sediment.

### **5.2.2 Recreational Child**

Table 5 presents exposure assumptions for a recreational child receptor, who is assumed to be exposed to CCB-derived COPCs where present in outdoor air via inhalation. In addition, the recreational child is assumed to be exposed to COPCs in surface water via dermal contact and sediment via incidental ingestion and dermal contact while playing in local ditches. Incidental ingestion

will not be evaluated for surface water due to the short exposure time for the wading scenario. This is consistent with the human health risk assessment conducted by USEPA Region I for the Wells G and H Superfund site (USEPA, 2004a). Fish ingestion is not expected to be a significant pathway for young children (aged 0 to 6). Data show that roughly 50% of children aged 0 to 9 years of age ingest little to no fish (USEPA, 1997a). Roughly 97% of children aged 0 to 9 years ingest less than 20 grams of fish per day (USEPA, 1997a). These statistics are for total fish consumption (freshwater, saltwater, and shellfish). Young and older children consume less than 3 grams of freshwater finfish per day based on the data in Table 10-6 of the EFH (USEPA, 1997a). USEPA Region I also concluded that this pathway is unlikely to occur with any degree of frequency for young children (USEPA, 2004a).

### **5.2.3 Recreational Fisher**

Recreational fishing may take place in local ditches. As constituents in groundwater may migrate to these water bodies, COPCs may be present in surface water, sediment, and fish tissue. Therefore, a recreational fisher has the potential to be exposed to COPCs through ingestion of fish and incidental ingestion and dermal contact with sediment and dermal contact with surface water. The recreational fisher is also assumed to be exposed to COPCs derived from CCBs where present in outdoor air via inhalation. The exposure assumptions for the fisher for the RME and CTE scenarios are summarized in Table 6.

### **5.2.4 Construction Worker**

Exposure assumptions for the construction/utility worker under the RME and CTE scenarios are shown in Table 7. Exposure media of interest in the evaluation of potential risk to a future construction worker will potentially include surface and subsurface CCBs where present and groundwater. Construction work is assumed to occur to a depth of 12 to 15 feet bgs and includes utility maintenance work. Where the water table surface lies within this interval, the construction worker will be evaluated for potential contact with COPCs in groundwater during excavation. Exposure could occur via dermal contact with CCB-derived constituents in groundwater and via inhalation of fugitive dust from CCBs. The CCB/soil ingestion rate listed in Table 7 for the construction worker under the CTE scenario is discussed in Section 5.3.3.

## **5.3 Exposure Assumptions**

The exposure assumptions presented in this Work Plan are derived mainly from USEPA guidance documents, including the EFH (USEPA, 1997a) and the Human Health Exposure Manual (USEPA, 1991a). Area of Investigation-specific considerations were used to develop certain exposure assumptions, such as direct contact with CCBs. Tables 4 through 7 present exposure assumptions for each of the receptors to be evaluated in the HHRA, along with the references for the derivation of these assumptions.

The following sub-sections provide additional detail regarding key exposure assumptions.

### **5.3.1 Frequency of Exposure to COPCs in CCBs**

For the purpose of this Work Plan, it has been assumed that CCBs are present in residential areas. Depending on the locations of surface CCBs within the Area of Investigation, the exposure frequency listed in Table 4 may be refined to more accurately reflect a hypothetical resident's exposure. The exposure frequency listed in Table 4 was developed to reflect meteorological conditions at the Area of Investigation, as described below.

A meteorological factor is generally used to account for the fraction of the year during which exposure to constituents at the ground surface may occur (Sheehan et al., 1991; USEPA, 1989a). It is reasonable to assume that direct contact with soil or CCBs or intrusive activities will not occur for residential receptors during inclement weather, i.e., when it is raining or snowing, when the ground is wet or frozen, or when snow or ice (32 degrees F) are covering the ground. Thus the frequency of contact with CCBs is adjusted for these location-specific meteorological conditions (USEPA, 1989a).

There are only a few metrics that can be used to describe the fraction of the year when meteorological conditions are likely to limit exposure. These include temperature and the amount of precipitation per day and per year, which includes rain, snow, and ice. The National Climatic Data Center (NCDC) provides daily temperature and precipitation data (NCDC, 1996). Daily temperature data are also available from the NIPSCO's Michigan City Generating Station (NIPSCO, 2005). It is assumed that exposure to CCBs is limited on days when the maximum temperature is less than 32 degrees F. The number of days with precipitation greater than 0.1 inches is selected as the best representation of when exposure is likely to be limited by snow, rain, or ice. The choice of a precipitation target of 0.1 inches is in keeping with guidance provided in the "Compilation of Air Pollution Emission Factors", which assumes that soil suspension will not occur on days with more than 0.01 inches of precipitation (USEPA, 1995b). It is probable, however, that this metric both over- and under-estimates the potential exposure in some conditions. For, example, it is possible that some exposure to CCBs may occur on days when it rains just over 0.1 inches in the early morning and then the ground dries during the course of the day. Alternatively, significant rainfall, such as greater than 1 inch, is likely to saturate the ground for consecutive days, and several inches of snow (which may fall all on one day with one storm) may cover the ground and inhibit direct contact for several days. With both of these considerations in mind, it is likely that a meteorological factor based on inclement days defined as precipitation greater than 0.1 inches and maximum temperatures less than 32 degrees F is reasonable.

Based on ten years of precipitation data (1995-2004) for South Bend, Indiana, National Weather Service (NWS) station at the Michiana Regional Airport (NCDC, 1996), and ten years of temperature data from the Michigan City Generating Station (1994-2004) a meteorological factor is derived for use in the exposure equations. South Bend, which is located 30 miles east of Michigan City, provides the

best data capture in the area for hourly precipitation data. Precipitation is not recorded at Michigan City Generating Station. The station at Brenton Harbor (40 miles northeast of Michigan City, but closer to Lake Michigan) has temperature data, but lacks precipitation data. While precipitation data sources closer to Michigan City are available, data capture is poor (i.e., Gary Airport, Ogden Dunes). While some difference in precipitation conditions from Michigan City to South Bend are expected, the differences are not expected to be significant. On the average, 69.6 days/year in this area receive 0.1 or greater inches of precipitation (NCDC, 1996), and there are typically 42.2 days/year with a maximum temperature of 32 degrees F or below (i.e., the temperature never rises above freezing during the day). Accounting for days when both events occur (3.6 days), the number of inclement days, 108.6, can be calculated ( $69.6 + 42.2 - 3.6$ ). It is assumed that these days are evenly spaced throughout the course of the year. The meteorological factor is then calculated ( $108.6/365 = 29.8\%$ ). Thus it is assumed that exposure to CCBs will not occur for the residential receptor 29.8% of the assumed days of exposure (exposure frequency) due to weather restrictions. This results in an exposure frequency of 245.9 (rounded up to 250) days per year for the RME residential scenario and 164.4 (rounded up to 165) days per year for the CTE residential scenario.

The use of the meteorological factor does not imply that no CCB exposure occurs on these days, only that exposure during those periods of precipitation greater than 0.1 inches and maximum temperatures less than 32 degrees F is negligible. It should be noted that this approach has precedence in regulatory risk assessment. Indiana (IDEM, 2001), Pennsylvania (PADEP, 1997) and Michigan (MDEQ, 2002) have modified the default exposure frequency to account for inclement weather in the development of screening standards for use in their environmental programs.

### **5.3.2 Surface Area and Soil to Skin Adherence Factors**

It is assumed that while outdoors, receptors will come into dermal contact with CCBs. Adherence estimates were calculated using the skin surface area data and soil adherence data from USEPA (1997a and 2004e). The methods used to derive the skin surface areas and adherence factors are described below.

#### **Surface Area**

For the adult resident, it is assumed that the head, hands, forearms, and lower legs are exposed for CCB contact. For the child resident, it is assumed that head, hands, forearms, lower legs, and feet are exposed for CCB and sediment exposure. Table 8 presents the 50<sup>th</sup> percentile surface areas for those body parts for an adult resident (5,700 cm<sup>2</sup>) and Table 9 presents the 50<sup>th</sup> percentile surface area for a child resident (2,800 cm<sup>2</sup>). The 50<sup>th</sup> percentile values are used because they correlate with the 50<sup>th</sup> percentile body weight parameter (e.g., 70 kg for adult) recommended by the USEPA (1989a). Additionally, these are the surface areas recommended in Exhibit 3-5 of USEPA (2004e).

It is assumed that construction workers are required to wear shoes and long pants. It is also assumed that the worker wears a long-sleeved shirt and/or coat during the colder months of the year and, at a minimum, a short-sleeved shirt during the warmer months of the year. Gloves are also likely worn in the winter. Therefore, the construction worker receptor's head, hands, and lower arms are conservatively assumed to be exposed for CCB contact throughout the year. Table 10 presents the surface areas for each of these body parts at the 50<sup>th</sup> percentile for adults. The total surface area assumed to be exposed is 3,300 cm<sup>2</sup>, which is consistent with the value recommended in Exhibit 3-5 of USEPA (2004e) for a commercial/industrial worker.

For the recreational fisher, it is assumed that hands, forearms, lower legs, and feet are exposed to sediment. Table 11 presents the 50<sup>th</sup> percentile surface areas for those body parts for a recreational fisher. The total surface area assumed to be exposed is 5,669 cm<sup>2</sup>.

### **Adherence Factors**

To account for differences in adherence for different parts of the body, an area-weighted adherence factor is calculated using the body part-specific adherence levels presented in Exhibit C-2 of USEPA (2004e). For each receptor, the skin surface area of each exposed body part is multiplied by its body part-specific adherence factor to yield a total mass adhered to that body part. The total masses are then summed for all exposed body parts, and then divided by the total body surface area exposed to derive the area-weighted adherence factor.

Estimates of adherence are derived from the EFH (USEPA, 1997a), which states that: "In consideration of ... the recent data from Kissel [Kissel et al., 1996]..., changes are needed from past USEPA recommendations [USEPA, 1992b] which used one adherence value to represent all soils, body parts, and activities. One approach would be to select the activity from Table 6-11 which best represents the exposure scenario of concern and use the corresponding adherence value from Table 6-12."

USEPA (2004e) indicates that adherence factors should be calculated by either selecting a central tendency soil contact activity and a high-end weighted adherence factor, or by selecting a high-end soil contact activity and using the central tendency weighted adherence factor. The guidance also states that using a high-end soil contact activity should not be used with a high-end weighted adherence factor, as this is not consistent with the use of an RME scenario.

From the exposure scenarios presented in Table 6-11 of USEPA (1997a) and the adherence data presented in Exhibit C-2 of USEPA (2004e), the following approach was used to derive adherence factors:

#### Adult Resident

- RME CCB Scenario – High-end soil contact activity (Gardeners) used with geometric mean adherence data =  $0.07 \text{ mg/cm}^2$  (consistent with recommendation in Exhibit 3-5 of USEPA, 2004e)
- CTE CCB Scenario – Central tendency soil contact activity (Groundskeepers) used with geometric mean adherence data =  $0.01 \text{ mg/cm}^2$  (consistent with recommendation in Exhibit 3-5 of USEPA, 2004e)

The calculations for the adult resident are presented in Table 8.

#### Child Resident/ Recreational Child

- RME Soil Scenario - High-end soil contact activity (Children Playing in Wet Soil) used with geometric mean adherence data =  $0.2 \text{ mg/cm}^2$  (consistent with recommendation in Exhibit 3-5 of USEPA, 2004e)
- CTE Soil Scenario - Central tendency soil contact activity (Day Care Kids) used with geometric mean adherence data =  $0.04 \text{ mg/cm}^2$  (consistent with recommendation in Exhibit 3-5 of USEPA, 2004e)
- RME and CTE Sediment Scenario - High-end soil contact activity (Children Playing in Wet Soil) used with geometric mean adherence data =  $0.2 \text{ mg/cm}^2$  (consistent with recommendation in Exhibit 3-5 of USEPA, 2004e)

The calculations for the child resident/recreational child are presented in Table 9.

#### Construction Worker

- RME Soil Scenario – High-end soil contact activity (Utility Workers) used with geometric mean adherence data =  $0.2 \text{ mg/cm}^2$  (consistent with recommendation in Exhibit 3-5 of USEPA, 2004e)
- CTE Soil Scenario – Central tendency soil contact activity (Groundskeepers) used with geometric mean adherence data =  $0.02 \text{ mg/cm}^2$  (consistent with recommendation in Exhibit 3-5 of USEPA, 2004e)

The calculations for the construction worker are presented in Table 10.

### Recreational Fisher

- RME and CTE Sediment Scenario – Adult sediment/wet soil contact activity (Reed Gatherers) used with geometric mean adherence data =  $0.3 \text{ mg/cm}^2$

The calculations for the recreational fisher are presented in Table 11.

#### **5.3.3 CCB Ingestion Rate**

Incidental soil ingestion occurs at all ages as a result of hand-to-mouth activities. Default soil or CCB ingestion rates will be used for the resident adult and child. However, currently, there are little or no reliable quantitative data available for estimating occupational adult soil ingestion rates. USEPA risk assessment guidance suggests a soil ingestion rate of 100 mg/day for adults in an outdoor industrial scenario (USEPA, 2001). Therefore, a CCB ingestion rate of 100 mg/day is used for the construction worker in the RME scenario. The following text describes the derivation of an alternative construction worker CCB ingestion rate for use in the CTE scenario.

CCB ingestion may occur as a result of hand-to-mouth transfer. Therefore, the amount of CCBs that may adhere to a receptor's hands is critical in determining the amount of CCBs that may be ingested by that receptor. In 1993, USEPA sponsored a workshop to evaluate soil-to-skin adherence data. A study to characterize soil-to-skin adherence was sponsored by the USEPA and conducted by John C. Kissel and associates at the University of Washington (Kissel et al., 1996; Holmes et al., 1999). The intent of this study was to resolve uncertainties and develop more accurate measures of soil-to-skin loading rates for various occupational and recreational activities. As reported in the EFH (USEPA, 1997a), soil loading on skin surfaces as a result of various occupational and recreational activities was directly measured. This study indicates that soil loadings vary with the type of activity and the body parts contacted. As one would expect, adherence appears to be greatest during outdoor activities such as farming and gardening, and more soil/dust tends to adhere to the hands and knees than to other areas of the body.

Average hand soil loading factors are as presented in the EFH (USEPA, 1997a) for the adult outdoor workers evaluated by Kissel and Holmes. The range of soil adherence loadings measured by Kissel and Holmes falls within the USEPA range of  $0.2$  to  $1.0 \text{ mg/cm}^2$  (USEPA, 1992b).

For this evaluation, the construction worker receptor is assumed to be exposed to COPCs in surface and subsurface CCBs during excavation activity. Based on this exposure scenario, the "farmer" receptor provided in the EFH is considered to provide an upper-bound estimate of adherence. An ingestion rate can be calculated by substituting the adherence value for the receptor for the estimated value derived by Hawley (1985), as follows:



$$\frac{480 \text{ mg / day}}{3.5 \text{ mg / cm}^2} = \frac{\text{ingestion rate (mg / day)}}{\text{soil adherence (mg / cm}^2\text{)}}$$

The soil to hand adherence value for the “farmer” is 0.47 mg/cm<sup>2</sup>. The calculated ingestion rate is 64 mg/day; therefore, an ingestion rate of 64 mg/day is used for the CTE construction worker receptor in this risk evaluation.

Additional support for this value comes from a paper by Kissel and coworkers (Kissel et al., 1998) that presents the results of a study of the transfer of soil from hand to mouth by intentional licking. Soil was loaded onto the skin by pressing the hand onto soil, and the amount transferred to the mouth was measured. The thumb sucking, finger mouthing, and palm licking activities resulted in geometric mean soil mass transfers of 7.4 to 16 mg per event. The author concludes that “transfer of 10 mg or more of soil from a hand to the oral cavity in one event is possible, but requires moderate soil loading and more than incidental hand-to-mouth contact.” However, “the fraction of soil transferred from hand to mouth that is subsequently swallowed is unknown but may be less than 100 percent.” In addition, “the adult volunteers in this study reported that the presence of roughly 10 mg of soil in the mouth is readily detected (and unpleasant). Repeated unintentional ingestion of that mass of soil by adults therefore seems unlikely.”

Therefore, for the CTE scenario, an ingestion rate of 64 mg/day is used for the construction worker. For the RME scenario, an ingestion rate of 100 mg/day is assumed for the construction worker. This is the adult soil ingestion rate provided by USEPA (1991a).

#### 5.4 Quantification of Potential Exposures

To estimate the potential risk to human health that may be posed by the presence of COPCs in the Area of Investigation, it is first necessary to estimate the potential exposure dose of each COPC. The exposure dose is estimated for each constituent via each exposure pathway by which the receptor is assumed to be exposed. Exposure dose equations combine the estimates of constituent concentration in the environmental medium of interest with assumptions regarding the type and magnitude of each receptor's potential exposure to provide a numerical estimate of the exposure dose. The exposure dose is defined as the amount of COPC taken into the receptor and is expressed in units of milligrams of COPC per kilogram of body weight per day (mg/kg-day).

Exposure doses are defined differently for potential carcinogenic and noncarcinogenic effects. The Chronic Average Daily Dose (CADD) is used to estimate a receptor's potential intake from exposure to a COPC with noncarcinogenic effects. According to USEPA (1989a), the CADD should be calculated by averaging the dose over the period of time for which the receptor is assumed to be exposed. Therefore, the averaging period is the same as the exposure duration.

For COPCs with potential carcinogenic effects, however, the Lifetime Average Daily Dose (LADD) is employed to estimate potential exposures. In accordance with USEPA (1989a) guidance, the LADD is calculated by averaging exposure over the receptor's assumed lifetime (70 years). Therefore, the averaging period is the same as the receptor's assumed lifetime.

The standardized equations for estimating a receptor's average daily dose (both lifetime and chronic) are presented below, followed by descriptions of receptor-specific exposure parameters and constituent-specific parameters.

#### **5.4.1 Estimating Potential Exposure to COPCs in Water**

The following equations are used to calculate the estimated exposure.

Average Daily Dose (Lifetime and Chronic) Following Ingestion of Water (mg/kg-day):

$$ADD = \frac{CW \times IR \times EF \times ED \times AAF_o}{BW \times AT}$$

where:

ADD	=	Average Daily Dose (mg/kg-day)
CW	=	Water Concentration (mg/L)
IR	=	Water Ingestion Rate (L/day)
EF	=	Exposure Frequency (days/year)
ED	=	Exposure Duration (year)
AAF <sub>o</sub>	=	Oral-Water Absorption Adjustment Factor (constituent-specific) (unitless)
BW	=	Body Weight (kg)
AT	=	Averaging Time (days)

Average Daily Dose (Lifetime and Chronic) Following Dermal Contact with Water (mg/kg-day):

$$ADD = \frac{CW \times SA \times PC \times ET \times EF \times ED \times AAF_d \times CF}{BW \times AT}$$

where:

ADD	=	Average Daily Dose (mg/kg-day)
CW	=	Water Concentration (mg/L)
SA	=	Exposed Skin Surface Area (cm <sup>2</sup> )
PC	=	Dermal Permeability Constant (PC) (cm/hr) (constituent-specific)
ET	=	Exposure Time (hours/day)
EF	=	Exposure Frequency (days/year)
ED	=	Years Exposed (year)
AAF <sub>d</sub>	=	Dermal-Water Absorption Adjustment Factor (constituent-specific) (unitless)
CF	=	Unit Conversion Factor (L/10 <sup>3</sup> cm <sup>3</sup> )
BW	=	Body Weight (kg)
AT	=	Averaging Time (days)

#### **5.4.2 Estimating Potential Exposures to COPCs in CCBs or Sediment**

The following equations are used to calculate the estimated exposure.

Average Daily Dose (Lifetime and Chronic) Following Incidental Ingestion of CCBs/Sediment (mg/kg-day):

$$ADD = \frac{CS \times SIR \times EF \times ED \times AAF_d \times CF}{BW \times AT}$$

where:

ADD	=	Average Daily Dose (mg/kg-day)
CS	=	Soil Concentration (mg/kg soil)
SIR	=	Soil Ingestion Rate (mg soil/day)
EF	=	Exposure Frequency (days/year)
ED	=	Exposure Duration (year)
AAF <sub>o</sub>	=	Oral-Soil Absorption Adjustment Factor (constituent-specific) (unitless)
CF	=	Unit Conversion Factor (kg soil/10 <sup>6</sup> mg soil)
BW	=	Body Weight (kg)
AT	=	Averaging Time (days)

Average Daily Dose (Lifetime and Chronic) Following Dermal Contact with CCBs/Sediment (mg/kg-day):

$$ADD = \frac{CS \times SA \times AF \times EF \times ED \times AAF_d \times CF}{BW \times AT}$$

where:

ADD	=	Average Daily Dose (mg/kg-day)
CS	=	Soil Concentration (mg/kg soil)
SA	=	Exposed Skin Surface Area (cm <sup>2</sup> /day)
AF	=	Soil to Skin Adherence Factor (mg soil/cm <sup>2</sup> )
EF	=	Exposure Frequency (days/year)
ED	=	Exposure Duration (year)
AAF <sub>d</sub>	=	Dermal-Soil Absorption Adjustment Factor (constituent-specific) (unitless)
CF	=	Unit Conversion Factor (kg soil/10 <sup>6</sup> mg soil)
BW	=	Body Weight (kg)
AT	=	Averaging Time (days)

#### 5.4.3 Estimating Potential Exposures to COPCs in Air

The equation used to estimate exposure to COPCs via inhalation is as follows.

Average Daily Dose (Lifetime and Chronic) Following Inhalation of COPC (mg/kg-day):

$$ADD = \frac{CA \times IR \times AAF_i \times ET \times EF \times ED}{BW \times AT}$$

where:

ADD	=	Average Daily Dose (mg/kg-day)
CA	=	Air Concentration (mg/m <sup>3</sup> )
IR	=	Inhalation Rate (m <sup>3</sup> /hr)
AAF <sub>i</sub>	=	Inhalation Absorption Adjustment Factor (constituent-specific) (unitless)
ET	=	Exposure Time (hours/day)

EF	=	Exposure Frequency (days/year)
ED	=	Exposure Duration (year)
BW	=	Body Weight (kg)
AT	=	Averaging Time (days)

#### **5.4.4 Estimating Potential Exposures to COPCs in Fish Tissue**

The equation used to estimate a receptor's potential exposure via fish consumption is:

Average Daily Dose (Lifetime and Chronic) Following Fish Consumption (mg/kg-day):

$$ADD = \frac{CF \times IR \times AAF \times EF \times ED}{AT \times BW}$$

where:

ADD	=	Average Daily Dose (mg/kg-day)
CF	=	Concentration in Food (mg/kg)
IR	=	Ingestion Rate (kg/day)
AAF	=	Oral-diet Absorption Adjustment Factor (constituent-specific) (unitless)
EF	=	Exposure Frequency (days/year)
ED	=	Exposure Duration (years)
AT	=	Averaging Time (days)
BW	=	Body Weight (kg)

### **5.5 Constituent-Specific Parameters**

Several of the parameters listed in the equations above are constituent-specific, and are further described below.

#### **5.5.1 Calculation of Exposure Point Concentrations**

Exposure points are located where potential receptors may contact COPCs at or from the Area of Investigation. The concentration of COPCs in the environmental medium that receptors may contact must be estimated in order to determine the magnitude of potential exposure.

Measured data will be available for CCBs, groundwater, surface water, and sediment. The 95% upper confidence limit of the mean (UCL) will be calculated using relevant and appropriate statistical methods based on the observed data distribution. The lower of the calculated UCL and the maximum detected concentration will be adopted as the exposure point concentration (EPC) for the RME scenario. A measure of central tendency (i.e., the arithmetic mean or other appropriate statistic) will be adopted as the EPC for the CTE scenario.

Other pathways will require modeling to derive exposure point concentrations. These pathways include generation of fugitive dust from undisturbed soils and during construction activities, and potentially calculation of game fish fillet constituent concentrations.

The calculation of concentrations of COPCs bound to CCBs in fugitive dust involves multiplying the soil exposure point concentrations by the concentration of dust in air as follows:

1) Ambient Air:

$$\text{COPC concentration in ambient air (mg/m}^3\text{)} = \text{Exposure point concentration in CCBs (mg/kg soil)} \\ \times \text{Dust concentration (kg soil/m}^3\text{)}$$

The dust concentration in air to be used in the evaluation of ambient outdoor air pathways in this risk evaluation is the inverse of the particulate emission factor (PEF) derived in accordance with USEPA guidance (USEPA, 1996a).

2) Excavation Air (i.e., during construction activities):

$$\text{COPC concentration in excavation air (mg/m}^3\text{)} = \text{Exposure point concentration in CCBs (mg/kg soil)} \\ \times \text{Dust concentration (mg soil/m}^3\text{)} \times \text{Unit correction factor (1 kg/10}^6\text{ mg)}$$

The dust concentration in air to be used in the evaluation of excavation air pathways in this risk evaluation is 60 ug/m<sup>3</sup>. This value is the recommended concentration of respirable particulate with a mean diameter of 10 microns or less (PM<sub>10</sub>) for excavation activities (MADEP, 1995).

USEPA (2001) provides a method for deriving dust concentrations for a construction worker scenario which is largely based on truck traffic on unpaved roads. However, the construction scenario evaluated for the Area of Investigation is more similar to a utility maintenance scenario, where some excavation may be required. Therefore, the above PM<sub>10</sub> scenario is more applicable to the scenario to be evaluated than the one recommended in USEPA, 2001.

### 5.5.2 Absorption Adjustment Factors

Absorption adjustment factors (AAFs) are used in risk assessment to account for absorption differences between humans exposed to substances in environmental situations and experimental animals in the laboratory studies used to derive dose-response values.

To estimate the potential risk to human health that may be posed by the presence of a substance in various environmental media (such as soil or groundwater) it is first necessary to estimate the human exposure dose of the constituent. The exposure dose is then combined with an estimate of the toxicity of the substance to produce an estimate of risk posed to human health.

The estimate of toxicity of a substance, termed the dose-response value, can be derived from human epidemiological data, but it is most often derived from experiments with laboratory animals. The dose-response value can be based on the administered dose of the substance (similar to the human exposure dose) or, when data are available, based on the absorbed dose, or internal dose, of the substance.

In animals, as in humans, the administered dose of a substance is not necessarily completely absorbed. Moreover, differences in absorption exist between laboratory animals and humans, as well as between different media and routes of exposure. Therefore, it is not always appropriate to directly apply a dose-response value to the human exposure dose. In many cases, a correction factor in the calculation of risk is needed to account for differences between absorption in the dose-response study and absorption likely to occur upon human exposure to a substance. Without such a correction, the estimate of human health risk could be over- or under-estimated.

This correction factor is termed the absorption adjustment factor, or AAF. The AAF is used to adjust the human exposure dose so that it is expressed in the same terms as the doses used to generate the dose-response curve in the dose-response study. The AAF is the ratio between the estimated human absorption factor for the specific medium and route of exposure, and the known or estimated absorption factor for the laboratory study from which the dose-response value was derived.

$$AAF = \frac{\text{(fraction absorbed in humans for the environmental exposure)}}{\text{(fraction absorbed in the dose - response study)}}$$

The use of an AAF allows the risk assessor to make appropriate adjustments if the efficiency of absorption between environmental exposure and experimental exposure is known or expected to differ because of physiological effects and/or matrix or vehicle effects.

AAFs can have numerical values less than one or greater than one, depending on the particular circumstances at hand. When the dose-response curve is based on administered dose data, and if it is estimated that the fraction absorbed from the location-specific exposure is the same as the fraction

absorbed in the laboratory study, then the AAF is 1. In the absence of detailed toxicological information on every constituent, it has been common practice for risk assessors to use a default AAF value of 1. However, use of AAFs in standard risk assessment calculations can provide more accurate and more realistic estimates of potential human health risk. The derivation of each non-default AAF used in the risk assessment will be provided in an appendix to the risk assessment report. The bioavailability protocol for arsenic (see Section 4.2 and Appendix B) may be used to develop an AAF for arsenic.

### **5.5.3 Skin Permeability Constants**

The estimation of exposure doses resulting from dermal contact with groundwater and/or surface water requires the use of a dermal permeability constant (PC) in units of centimeters per hour (cm/hr). This method assumes that the behavior of constituents dissolved in water is described by Fick's Law. In Fick's Law, the steady-state flux of the solute across the skin ( $\text{mg}/\text{cm}^2/\text{hr}$ ) equals the permeability constant (PC, cm/hr) multiplied by the concentration difference of the solute across the membrane ( $\text{mg}/\text{cm}^3$ ). This approach is discussed by USEPA (USEPA, 1989a; 2004e).

PC values will be derived from USEPA's "Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment, Final)" (USEPA, 2004e).

### **5.5.4 Bioconcentration Factors**

If conditions in the ditches in the Area of Investigation are such that they could sustain a recreational fishery, bioconcentration factors (BCFs) will be used to estimate fish tissue concentrations based on COPC concentration in surface water using the following equation, unless fish tissue samples are collected:

$$\text{Fish Tissue Concentration (mg/kg)} = \text{BCF (L/kg)} \times \text{Surface Water Concentration (mg/L)}$$

BCFs will be developed in accordance with the project ecological risk assessors. In addition, based on consultation with the project ecological risk assessors, consideration will be made of the use of biota-sediment accumulation factors (BSAFs) for calculating fish tissue concentrations.



## 6.0 RISK CHARACTERIZATION

The purpose of the risk characterization is to provide estimates of the potential risk to human health from exposure to COPCs. To accomplish this objective, this section will include quantitative estimates of potential carcinogenic and noncarcinogenic risk.

The results of the exposure assessment are combined with the results of the dose-response assessment to derive quantitative estimates of risk, or the probability of adverse health effects following assumed potential exposure to the COPCs. Using the exposure point concentrations derived in the exposure assessment, each exposure pathway for each receptor will be evaluated as appropriate for potential carcinogenic or noncarcinogenic effects.

### 6.1 Cumulative Risk

Total risks will be calculated for each receptor. COCs for potentially carcinogenic and noncarcinogenic effects will be identified, and pathways that contribute significantly to target risk exceedances will be identified, as discussed below.

### 6.2 Carcinogenic Risk Characterization

The purpose of carcinogenic risk characterization is to estimate the upper-bound likelihood, over and above the background cancer rate, that a receptor will develop cancer in his or her lifetime as a result of exposure to a constituent in an environmental medium. This likelihood is a function of the dose of a constituent (described in the Exposure Assessment) and the CSF (described in the Dose-Response Assessment) for that constituent. The American Cancer Society (ACS) estimates that the lifetime probability of contracting cancer in the U.S. is 1 in 2 for men and 1 in 3 for women (ACS, 2004). The Excess Lifetime Cancer Risk (ELCR) is the likelihood over and above the background cancer rate that an individual will contract cancer in his or her lifetime. The risk value is expressed as a probability (e.g.,  $10^{-6}$ , or one in one million). For an ELCR of  $10^{-6}$ , an individual would have a 1 in one million chance of developing cancer in addition to the 1 in 2 or 1 in 3 chance estimated by the ACS. The relationship between the ELCR and the estimated LADD of a constituent may be expressed as:

$$\text{ELCR} = 1 - e^{-(\text{CSF} \times \text{LADD})}$$

If the product of the CSF and the LADD is much greater than 1, the ELCR approaches 1 (i.e., 100 percent probability). If the product is less than 0.01 (one chance in 100), the equation can be closely approximated by:

$$\text{ELCR} = \text{LADD (mg/kg-day)} \times \text{CSF (mg/kg-day)}^{-1}$$

The product of the CSF and the LADD is unitless, and provides an upper-bound estimate of the potential carcinogenic risk associated with a receptor's exposure to that constituent via that pathway.

The potential carcinogenic risk for each exposure pathway will be calculated for each receptor. In current regulatory risk assessment, it is assumed that cancer risks are additive or cumulative. Pathway and area-specific risks are summed to estimate the total potential cancer risk for each receptor. A summary of the total cancer risks for each receptor group will be presented in this section of the HHRA.

USEPA has established target risk levels under the NCP (USEPA, 1990). Target risk levels refer to levels of cancer risk or hazard indices that are deemed acceptable by the USEPA or other regulatory agencies. These are levels below which the potential for adverse effects to humans are assumed to be negligible or inconsequential. The NCP establishes a target cancer risk range of  $10^{-4}$  to  $10^{-6}$  and a target hazard index of less than or equal to one (USEPA, 1990). The USEPA subsequently clarified that, "Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than  $10^{-4}$ , and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted, unless there are adverse environmental impacts" (USEPA, 1991b).

Therefore, the screening levels used to identify COPCs are based on a  $10^{-6}$  risk level, and a cumulative target risk level of  $10^{-4}$  will be used to evaluate the risk assessment results. COCs will be identified sequentially as follows:

1. Any COPC with a potential risk greater than  $10^{-4}$ , if any, will be identified as a COC;
2. The total potential risk of the remaining COPCs will be calculated;
3. If the total potential risk is greater than  $10^{-4}$ , the COPC with the highest potential risk will be selected as a COC;
4. This process will continue until the total potential risk for the remaining constituents is less than  $10^{-4}$ .

Both RME and CTE results will be considered in the identification of COCs.

### **6.3 Noncarcinogenic Risk Characterization**

The potential for exposure to a constituent to result in adverse noncarcinogenic health effects is estimated for each receptor by comparing the CADD for each COPC with the RfD for that COPC. The resulting ratio, which is unitless, is known as the Hazard Quotient (HQ) for that constituent. The HQ is calculated using the following equation:

$$HQ = \frac{CADD \text{ (mg/kg - day)}}{RfD \text{ (mg / kg - day)}}$$

The target HQ is defined as an HQ of less than or equal to one (USEPA, 1989a). When the HQ is less than or equal to one, the RfD has not been exceeded, and no adverse noncarcinogenic effects are expected. If the HQ is greater than one, there may be a potential for adverse noncarcinogenic health effects to occur; however, the magnitude of the HQ cannot be directly equated to a probability or effect level.

The total Hazard Index (HI) is calculated for each exposure pathway by summing the HQs for each individual constituent. The total HI will be calculated for each potential receptor by summing the HIs for each pathway associated with the receptor. If the total HI is greater than one for any receptor, a more detailed evaluation of potential noncarcinogenic effects based on specific health endpoints will be performed (USEPA, 1989a).

A summary of all HI for each receptor group will be presented and compared to the USEPA's target HI of one. Any COPC that causes an exceedance of the HI of 1 for a particular receptor and target endpoint will be designated a COC. Both RME and CTE results will be considered in the identification of COCs.

#### **6.4 Risk Assessment Refinement**

The HHRA will utilize the conservative exposure and dose-response parameters described here. When results of the HHRA are reviewed, the risk drivers and COCs, if any, will be identified. Risk estimates will then be refined by using, for example, the following: location-specific exposure data (e.g., creel census), location-specific bioavailability factors, or probabilistic (or Monte Carlo) analysis. Use of such refinements, such as a probabilistic risk assessment, will allow the risks to be put in perspective and will provide information that the risk manager needs to more accurately characterize risks on a location-specific basis and to communicate the nature of the risks.

#### **6.5 Uncertainty Analysis**

Uncertainty is introduced into the risk assessment in several places throughout the process. Every time an assumption is made, some level of uncertainty is introduced into the risk assessment. In accordance with USEPA guidance (USEPA, 1989a), the uncertainty associated with each step of the risk characterization process will be discussed in this section of the report.

There are many potential sources of uncertainty in the risk assessment process; some are more important than others. The major areas of uncertainty include: the quality of the analytical data, assumptions about the frequency, duration, and magnitude of exposure, the receptors identified, assumptions made in the modeling performed to predict concentrations at locations where

measurement data are lacking, and the availability and accuracy of dose-response data. The uncertainties will be discussed qualitatively in the report, including steps taken to compensate for uncertainty, and the impact on the risk assessment results.

## **7.0 SUMMARY AND CONCLUSIONS**

The summary and conclusions section of the HHRA will contain discussions of the results of the risk assessment. The selection of final COCs will be presented.

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